

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

ERNEST K. MANDERS, M.D.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action 02-1341
	)	
MCGHAN MEDICAL CORPORATION, a	)	
Subsidiary and or division of INAMED	)	
CORPORATION a Delaware Corporation,	)	
INAMED MEDICAL PRODUCTS	)	
CORPORATION A SUBSIDIARY AND	)	
OR DIVISION OF INAMED	)	
CORPORATION A CALIFORNIA	)	
CORPORATION,	)	
	)	
Defendants.	)	

**MEMORANDUM OPINION**

**Conti, J.**

Ernest K. Manders, M.D. (“Manders” or “plaintiff”) brings this patent infringement action against McGhan Medical Corporation (now known as “Inamed Medical Products Corporation”) and Inamed Medical Products Corporation (collectively, “defendants”). Manders is the owner of United States Patent No. 4,574,780 (the “‘780 patent”) entitled “Tissue Expander and Method,” issued on March 18, 1986 to Manders. Manders alleges that defendants make and sell certain breast tissue expanders which infringe the ‘780 patent. Defendants deny infringing the ‘780 patent and counterclaim for declaratory relief, seeking, among other things, a declaration that the ‘780 patent is invalid and was not infringed by defendants. Jurisdiction and venue are proper in this district. See 28 U.S.C. §§ 1331, 1338(a), 1332(a), 1391(b), 1400(b).

Pending before the court is the patent claim construction dispute. The parties briefed their positions and a Markman hearing was held before this court on September 23, 2004, October 7, 2004 and October 18, 2004. This opinion addresses the proper interpretation of the claim phrases in dispute.

## **I. BACKGROUND**

Manders is the inventor of the '780 patent and is employed as a professor of surgery at the University of Pittsburgh Medical Center. His academic and clinical careers focus on reconstructive surgery. When Manders was a chief resident he began carrying out tissue expansion to reconstruct a nose and later scalps. He determined to develop a directional or differential expander that would be used to reconstruct male pattern baldness. In November 1984 Manders filed for a patent. The patent was issued on March 11, 1986.

The '780 patent discloses a differential soft tissue expander device used to create new tissue for plastic and reconstructive surgery. When the device is implanted below the patient's soft tissue and saline is injected into the device through an injection port, the fluid forces the device and the overlying tissue to expand from the pressure and create new tissue.

Prior to the issuance of the '780 patent, expanders having uniform covers only allowed for creation of generally uniform length tissue flaps. While these devices were useful for many types of surgeries, the ability to form a differential width flap greatly enhances the usefulness of the expansion procedures by allowing the expanded flap to be applied to non-planar or non-uniform length areas.

The '780 patent was designed to allow creation of differential width flaps for greater flexibility in uses, such as treating male pattern baldness or breast mound reconstruction. The differential expansion is achieved through the use of two portions in the expander device. The first portion allows limited expansion, while the second, adjacent portion allows greater expansion when additional fluid is added.

## II. GENERAL PRINCIPLES OF CLAIM CONSTRUCTION

Patent claim construction is a matter of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995). The analysis begins with the words of the claim. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996); see Nystrom v. Trex Co., Inc., 424 F.3d 1136, 1142 (Fed. Cir. 2005)(citing Vitronics Corp.). Generally, claim terms take on their ordinary and customary meaning as understood by those of ordinary skill in the art at the time of invention. Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc., 381 F.3d 1111, 1116 (Fed. Cir. 2001); Nystrom, 424 F.3d at 1142 (“The person of ordinary skill in the art views the claim in the light of the entire intrinsic record.”). Sometimes the ordinary meaning of a claim term can be readily apparent, in which case claim construction may involve “little more than the application of the widely accepted meaning of commonly understood words.” Phillips v. AWH Corp., 415 F.3d 1303, 1314 (Fed. Cir. 2005)(*en banc*). In more complicated situations, to find the ordinary meaning as given to the claim terms by one of the ordinary skill in the art, the claims are read in light of the intrinsic evidence, including the written description, the drawings, and the prosecution history, if in evidence. Teleflex, Inc. v. Ficosa North America Corp., 299 F.3d 1313, 1324 (Fed. Cir. 2002). The focus of the analysis, however, must remain centered on the language

of the claims. Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1248 (Fed. Cir. 1998). “[T]he context in which a term is used in the asserted claim can be highly instructive.” Phillips, 415 F.3d at 1314. Other claims, both asserted and unasserted, may also be helpful in construing claim terms, since claim terms are generally used consistently throughout the patent. Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 (Fed. Cir. 2001). The specification is “highly relevant” and usually dispositive. Phillips, 415 F.3d at 1315 (quoting Vitronics, 90 F.3d at 1582).

The ordinary meaning of the claim terms as understood by one of ordinary skill in the art can be restricted in one of four situations: (1) if the patentee acted as his own lexicographer and clearly set forth a different definition in the specification, (2) if the patentee distinguished that term from the prior art thereby expressly disclaiming certain subject matter, (3) if the term chosen deprives the claim of clarity such that reference to the specification for meaning is required, or (4) if the patentee phrased the claim in step- or means-plus-function format. CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366-67 (Fed. Cir. 2002). It is inappropriate for the court to import a limitation found solely in the written description into the claim. Markman, 52 F.3d at 980. “We do not import limitations into claims from examples or embodiments appearing only in a patent’s written description, even when a specification describes very specific embodiments of the invention or even describes only a single embodiment unless the specification makes clear that the ‘patentee . . . intends for the claims and the embodiments in the specification to be strictly coextensive.’” JVW Enterprises, Inc. v. Interact Accessories, Inc., 424 F.3d 1324, 1335 (Fed. Cir. 2005) (quoting Phillips, 415 F.3d at 1323).

### III. DISCUSSION – CLAIM CONSTRUCTION

The ‘780 patent includes 46 claims. The parties selected apparatus claim 31 and method claim 24 as representative of the claimed invention. Also asserted are claims 32, 33, 34, 35, 37, 39, 40, 44, 46, and 25. Plaintiff is electing to limit the claims in issue in this litigation to those claims and reserves the right to seek to amend the list of claims in issue. Defendant reserves the right to contend that any claim not asserted by plaintiff should be deemed dismissed with prejudice.

#### A. Claim 31

The preamble of claim 31 reads:

*A soft tissue expander device adapted to be implanted collapsed beneath a soft tissue layer of skin and subcutaneous tissue,*

A preamble limits the claimed invention if it recites essential structure or steps, or if it is necessary to give life, meaning and vitality to the claim. Eaton Corp. v. Rockwell Int’l Corp., 323 F.3d 1332, 1339 (Fed. Cir. 2003). Additionally, if limitations in the body of the claim rely upon and derive antecedent basis from the preamble, the preamble may act as a limitation of the claimed invention. 323 F.3d at 1339 (structure identified in the preamble was referred to in the body of the claim with the definite articles “the” or “said”). If, however, the body of the claim sets out the complete invention, then the language of the preamble is not limiting. Id. at 1339.

The only claim limitation which appears to derive antecedent basis from the preamble is “a soft tissue layer of skin and subcutaneous tissue,” which is referred to later in the body of the claim as “the layer of skin and subcutaneous tissue.” Despite this, the preamble in this case does not appear to give any additional scope or meaning to the construction of the claim and,

therefore, the preamble will not be considered limiting.

The transition of claim 31 reads:

*the device comprising*

The parties agree to the construction “the device including but not limited to the following.”

Claim 31 continues:

*flexible wall means defining a fluid impervious chamber,*

The parties agree that even though this limitation uses the word “means,” it recites sufficient structure to take it outside of the means-plus-functions limitation recognized by 35 U.S.C. § 112, ¶ 6. Both parties also agree that the wall means is pliable, demarcates an enclosed space and does not allow fluids to pass through. Therefore, the court finds this limitation to mean “a pliable barrier that demarcates an enclosed space and does not allow fluids to pass through.”

Claim 31 continues:

*and an injection port communicating with the interior of the chamber for  
admitting fluid into the chamber to expand the chamber,*

The parties agree that the injection port has an opening connected to the interior of the chamber that allows fluid to enter the chamber. The court finds that this limitation means “a sealable opening, located either remote from or in the flexible wall means, connecting to the interior of the chamber allowing the entrance of fluid into the chamber to expand the chamber.”

Claim 31 continues:

*said wall means including an expandable cover in contact with the layer of skin and subcutaneous tissue when the device is implanted,*

The parties agree that the wall means includes a portion that is capable of increasing in size or area. The parties disagree as to how “contact” should be construed.

The specification only discusses the device as being implanted “beneath the skin and subcutaneous tissue”, col. 2, line 9; col. 3, lines 11-23, of the port “facing” the skin, col. 4, line 60, and of the base “paralleling and facing away from the overlying soft tissue” col. 4, lines 56-58. There is no discussion of how the cover “contacts” the skin and subcutaneous tissue, but it is impossible for the cover to be in direct contact with both the skin and the tissue. The word “contact” in this context is most clearly understood as used in place of “facing.”

The court finds this limitation means “a portion of the wall means that can be increased in size which would face the layer of skin and subcutaneous tissue when implanted.”

The next limitation in claim 31 requires:

*the cover including a first limited expansion portion expandable by initial fluid injected through the port and into the chamber from a collapsed implantation position to a taut position above the collapsed position*

The parties agree that the limited expansion portion is a part of the cover that is expandable by the initial fluid injected through the port and into the chamber from a collapsed implantation position to a taut or tight position above the collapsed position. Defendants, however, would like to construe “collapsed” as meaning “compactly folded” while the plaintiff

would like to construe “collapsed” as meaning “folded down to a more compact shape or closed together.”

The parties disagree as to the interpretation of “collapsed” as used in both claim 31 and claim 24. Generally, the same word in a patent has the same meaning each time it is used. Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1345 (Fed. Cir. 1998). The written description notes both embodiments where the cover is folded when collapsed (col. 3, lines 63-64; col. 4, lines 54-55) and where it is not folded (col. 7, lines 44-46). The second mention of “collapsed” comes when the written description notes that the surgeon is to “withdraw the saline solution” from the chamber to collapse it. (Col. 5, lines 33-34)(emphasis added). Since this phrase does not say that “some saline” is removed, or even simply “saline” is removed, it implies that all of the saline solution in the device is removed. The “conventional manner” for the method of implantation, however, is referred to twice in the written description. (Col. 2, lines 22-24; col. 6, lines 53-54). It may be important to understand the “conventional manner” before the possibility of a non-completely emptied “collapsed position” could be completely excluded from the scope of this patent.

The court finds this limitation means “the cover including a portion that is capable of increasing in size by the initial fluid injected through the port and into the chamber from collapsed implantation position to a taut position over the collapsed position” where “collapsed,” at this time and without the knowledge of the “conventional manner,” means the device is empty of fluid.



The next limitation in claim 31 provides:

*and a second differential expansion portion adjacent said limited expansion portion expandable by said initial injected fluid with the limited expansion portion above the collapsed implantation position*

The parties agree that the differential expansion portion is a second portion or part of the cover capable of expanding further than the limited expansion portion and that can expand with the limited expansion portion by the initial injected fluid above the collapsed position. The written description only describes the two cover portions as being “joined,” col.2, lines 4-7, and all the figures show that limited expansion portion next to or connected to the differential expansion portion. It appears that for this particular term, the general usage of the word “adjacent” is what the inventor intended.

The court finds this limitation means “another portion of the cover, joined to the limited expansion portion either directly or through a tapered portion, capable of expanding differently from but expandable with the limited expansion portion by the initial injected fluid above the collapsed position.”

Claim 31 continues:

*said limited expansion portion including limiting means preventing further expansion of such portion beyond said taut position by further fluid injected into the chamber in addition to the initial injected fluid*

Both parties agree that this limitation should be interpreted as a means-plus-function claim. To construe a means-plus-function claim limitation, the first step is to define the particular function of the claim limitation. Golight, Inc. v. Wal-Mart Stores, Inc., 355 F.3d 1327,

1333 (Fed. Cir. 2004). The function must include only limitations contained in the claim language and the language of the claim is interpreted under ordinary principles of claim construction. Id. at 1333-34. After the function is identified, the specification is then reviewed to identify the corresponding structure for that function. Id. Structure is corresponding only if the specification clearly associates that structure to the function recited in the claim. Id.

In this case, the claimed function is to prevent further expansion beyond the taut position. See Golight, 355 F.3d at 1334 (holding that the claimed function of a means-plus-function limitation at issue was contained in language set forth after the word “means”). Nothing in the language of claim 31 nor the specification requires that “prevent” be limited to “keep from happening.” Words used when describing the expansion in the written description are not in absolute terms, but are relative. Reference to the written description finds such phrases as “expands the weak differential expansion portion of the cover without appreciably further expanding the strong limited expansion portion of the cover,” col. 2, lines 26-29, that the limited expansion portion is “essentially dimensionally stable,” col. 4, lines 42-45, and that the “thick, limited expansion cover portion withstands the pressure without appreciable expansion,” col. 5, lines 7-8. Reading the claim in light of the specification, it is clear that preventing means can include a range of levels of prevention.

After identifying the claimed function, the specification is reviewed for identification of corresponding structures that perform the function of preventing further expansion of the limited expansion means. Golight, 355 F.3d at 1333. Examining the specification for possible structures, a relatively thick limited expansion portion is disclosed (“limited expansion portion of the cover away from [the differential] expandable portion has an increased thickness and is

stronger than [the differential expansion portion] . . . [the limited expansion portion] is essentially dimensionally stable and does not expand beyond the taut position”, col. 4, lines 42-46), with either a uniform thickness for the limited expansion portion (“the cover includes a thick uniform thickness”, col. 5, lines 59-60) or a tapered thickness (“with a tapered cover”, col. 4, line 21). Another embodiment shows the use of multiple layers to increase thickness (“the cover is formed of a number of discrete bonded layers . . . so that the thickness of the cover decreases in steps” col. 5, lines 47-49). As an alternative, a reinforced limited expansion portion is disclosed (“device 72 having a reinforced limited expansion cover portion 74” . . . “portion 74 does not expand beyond the portion of Fig. 13”, col. 5, 65-66 and col. 6 lines 14-15). Those are the only structures necessary for the limiting means to prevent further expansion of the limited expansion cover.

This is similar to the situation in Golight, which involved a means-plus-function claim where the specification only showed embodiments which rotated through 360 degrees. 355 F.3d at 1333. The court of appeals agreed with the district court, which had found that the claim did not contain a 360-degree limitation; therefore, to read one into the claim was impermissible. Id. The court found that particular structures for permitting rotation through 360 degrees were “superfluous to [their] claim construction analysis because they are not required for performing the claimed function” of “rotating said lamp unit in a horizontal direction.” Id. at 1334.

To fulfill the function of preventing further expansion of the limited expansion portion of the cover, the preventing means must be included in the limited expansion portion. In the specification, the limited expansion portion is only disclosed as going from one side of the base to the other. Since the limited expansion portion, however, is not claimed in means-plus-

function format, it is limited only by what the claim language itself requires. Texas Digital Systems, Inc. v. Telegenix, 308 F.3d 1193, 1205 (Fed. Cir. 2002) (if the words of the claims would not be understood to be limited to the embodiments described in specification, reading limitations into the claims is impermissible). Nowhere in claim 31 is a base required, nor is the limited expansion portion of the cover required to go from one side of the base to the other. Additionally, since the limited expansion portion and the differential expansion portions are not claimed in means-plus-function format, claim differentiation can be applied to the limited expansion portion and the differential expansion portion. Claim 32 specifies a device wherein one cover portion (the limited or differential expansion portion) extends across from base edge to base edge. Therefore, neither cover portion is required to extend from one side of the base to the other under claim 31. The claim requires only that the limited expansion portion is adjacent to the differential expansion portion, both of which are capable of expanding and are located in the cover which is in the wall means, col. 11, lines 26-34.

The court finds the function of the preventing means is “to hinder further expansion of the limited expansion portion” and the corresponding structures for this function are a thickened limited expansion portion with either a uniform or tapered structure, a reinforced limited expansion portion, or multiple bonded layers of material for the limited expansion cover portion.

Claim 31 continues:

*said differential expansion portion including expansion means permitting further expansion of such portion by said further fluid*

The parties agree this limitation also should be construed as a means-plus-function claim, and generally agree that the function is “allowing expansion of the differential expansion portion

by injection of fluid in addition to the initial fluid.” The parties, however, disagree on the premise that this forbids any expansion of the limited expansion portion from the additional fluid and the structure that is attributed to this expansion means.

The specification demonstrates the relationship between the preventing means and the permitting means in one particular embodiment. It is stated that “[t]he thick, limited expansion cover portion 34 withstands the pressure without appreciable expansion. The thinner, differential expansion cover portion 32 expands in response to the increased pressure.” Col. 5, lines 7-10. While this is only one embodiment, it shows the interaction of the two means and helps clarify the correlating structures found in the written description.

Consistent with the court’s construction of the limiting means clause above, and the specification, the court finds that the function of the expansion means is “to allow expansion of the differential expansion portion by injection of said further fluid” and that potential correlating structures are a relatively thin differential expansion cover portion, col. 4 lines 34-35, and an unreinforced or reinforced differential expansion cover portion that is larger in area than the limited expansion portion, col. 5, lines 65-67 and col. 6, lines 16-17.

Finally, claim 31 ends:

*whereby fluid injected through the port and into a chamber of an implanted device first expands both the first and second cover portions together with the tissue overlying such portions and then further expands the second cover portion together with the tissue overlying the second cover portion only to form a differentially expanded tissue flap.*

The parties disagree as to whether this whereby clause constitutes a claim limitation. Generally, if the whereby clause only states the result of the claim limitations, it does not constitute a limitation itself. Texas Instruments Inc. v. U.S. Intern. Trade Com'n, 988 F.2d 1165, 1172 (Fed. Cir.1993) (“A ‘whereby’ clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim.”). This is precisely one of those situations. The clause deals only with the result of the claim limitations and, therefore, is not a limitation itself.

Even taking into account the language of the clause, the “only” that defendants place a great deal of importance on refers only to the overlying tissue covering the differential expansion portion, rather than both the differential expansion portion and the overlying tissue due to its sentence structure (“whereby fluid injected through the port and into a chamber of an implanted device first expands both the first and second cover portions together with the tissue overlying such portions and then further expands the second cover portion together with the tissue overlying the second cover portion only to form a differentially expanded tissue flap”). If the second cover portion were to also be affected by the modifier “only,” the sentence would need to be rewritten (i.e., “. . . further expands only the second cover portion together with the tissue overlying the second cover portion . . .”).

#### **B. Claim 32**

*A device as in claim 31 wherein one cover portion extends across the cover.*

The parties agree that this limitation is construed as “a device as in claim 31 wherein at least one portion of the cover (i.e., limited expansion portion or differential expansion

portion) reaches from one side of the device adjoining the base to the other side of the device adjoining the base.”

**C. Claim 33**

*A device as in claim 31 wherein said limited expansion portion extends across the cover.*

The parties agree that this limitation is construed as “a device as in claim 31 wherein the limited expansion portion of the cover reaches from one side of the device adjoining the base to the other side of the device adjoining the base.”

**D. Claim 34**

*A device as in claim 33 wherein the differential expansion portion is formed from an elastomer material and is bulbous in shape when such portion is fully expanded.*

The parties agree that the differential expansion portion is formed of a substance which is rubber like and resembles a bulb when it is fully expanded. The court finds this phrase is construed as “a device as in claim 33 wherein the differential expansion portion is formed from a substance having the elastic properties of rubber and resembling a bulb shape when it is fully expanded.”

**E. Claim 35**

*A device as in claim 31 wherein both cover portions extend across the cover.*

The parties generally agree that both the limited expansion portion and the differential expansion portion of the cover reaches or stretches from one side of the device adjoining the base to the other side of the device adjoining the base. The court finds this

limitation to be construed as “a device as in claim 31 wherein both the limited expansion portion and the differential expansion portion of the cover reach from one side of the device adjoining the base to the other side of the device adjoining the base.”

**F. Claim 37**

*A device as in claim 31 wherein the cover is formed of an elastomer material.*

The parties agree that the cover is formed of an elastic rubber-like material. The court finds this limitation means “a device as in claim 31 wherein the cover is formed from a substance having the elastic properties of rubber.”

**G. Claim 39**

*A device as in claim 37 wherein the differential expansion portion is thinner than the limited expansion portion.*

The parties agree to the construction “a device as in claim 37 wherein the differential expansion portion has comparatively lesser overall thickness than the limited expansion portion.”

**H. Claim 40**

*A device as in claim 39 wherein the thickness of the differential expansion portion decreases in a direction away from the limited expansion portion.*

The court finds that this limitation means “a device as in claim 39 wherein the differential expansion portion has a lesser thickness at a point further from the limited expansion portion than it does at a point closer to the limited expansion portion.”



**I. Claim 44**

*A device as in claim 31 wherein the port is formed in the limited expansion portion of the cover.*

The parties agree to the construction “a device as in claim 31 wherein the port is located within the limited expansion portion of the cover.”

**J. Claim 46**

*A device as in claim 31 wherein the wall means includes a dimensionally stable base.*

The parties essentially agree that the wall means includes a part that is resistant to sudden change in width or length. The court finds this limitation means “a device as in claim 31 wherein the wall means includes a lower or bottom part that is resistant to sudden change in width or length.”

**K. Claim 24**

The preamble of claim 24 reads:

*A surgical method of expanding and applying soft tissue by use of a soft tissue expander device having an expandable cover*

Again, this preamble adds nothing of value to the construction of this claim. Consistent with the discussion above, this preamble should not be read as a limitation.

The transition of claim 24 reads:

*comprising the step of:*

The parties agree that this is interpreted as the “method including but not limited to the following steps performable in any order unless inherently demanded by the nature of the step.”

The parties disagree as to whether the order of the steps is fixed by the claim. Generally, steps are not fixed in the order presented unless the steps of the method actually require an order. Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1342 (Fed. Cir. 2000). When the method steps, however, implicitly require that they be performed in the order as laid out in the claim, that order becomes fixed. Id. Defendants claim that since it only makes sense that step (f) be performed after step (e), this fixes the order of the steps to the way they are listed in the claim. Plaintiff claims that the steps may occur in any order. It is not absolutely necessary that (e) (collapsing and removing) be performed before (f) (severing edges). In fact, one could envision a situation where the surgeon may sever the edges of the expended layer in order to facilitate the removal process. Therefore, the court interprets this claim as not requiring steps (e) and (f) to be performed in the stated order.

Limitation (a) in claim 24 reads:

*(a) Separating a layer of skin and subcutaneous soft tissue connected to surrounding skin and soft tissue from underlying support tissue to form a pocket*

The parties agree that “separating” is interpreted as “spacing apart.” The parties disagree whether “a layer of skin” means “a single thickness.” In construing open-ended claims, “a” has been found to mean “one or more.” KCJ Corp. v. Kinetic Concepts, Inc., 223 F.3d 1351, 1356 (Fed. Cir. 2000). Therefore, “a layer of skin” is not limited to “a single layer of skin.”

This court finds this limitation means “spacing apart the skin and loose connective tissue located just beneath the skin connected to surrounding skin and soft tissue from the support tissue lying beneath to create a pocket.”

Claim 24 continues with limitation (b):

*(b) Placing a collapsed soft tissue expander device in the pocket with the cover of the device facing the separated tissue layer;*

Consistent with the earlier construction of “collapsed,” the court finds this limitation to mean “placing a collapsed soft tissue expander device in the pocket with the cover of the device facing the separated tissue layer,” where “collapsed,” at this time and without the knowledge of the “conventional manner,” means the device is empty of fluid.

Claim 24 continues with limitation (c):

*(c) Forcing the cover against the separated tissue to expand the tissue layer substantially uniformly away from the underlying tissue;*

The parties agree that this limitation requires moving or pushing the cover against the separated tissue away from the underlying tissue. They also agree that “substantially uniformly” requires all but minor variations. The court finds this limitation to mean “pushing the cover against the separated tissue to expand the tissue layer consistently, but with acceptable minor variations, from the underlying tissue.”

Limitation (d) in claim 24 reads:

*(d) Retaining a first portion of the cover in the expanded position and further forcing a second portion of the cover against the overlying portion of the separated tissue layer to further expand such overlying portion only;*

The parties agree that this limitation requires one portion to keep in a particular position and further moves or pushes a second part of the cover against a portion of the separated tissue that lies over it. The disagreement comes with respect to the interpretation of “retaining.”

The parties agree that “retain” means to keep in a particular position. Defendants claim, however, that this term should be construed so that it precludes any further expansion of the limited expansion portion. In this vein, defendants again seize on the word “only” at the end of the limitation (“retaining a first portion of the cover in the expanded position and further forcing a second portion of the cover against the overlying portion of the separated tissue layer to further expand such overlying portion only”). The structure of the sentence, however, is even more clear in its indication that the word “only” applies only to the overlying tissue portion. Plaintiff, asserts that the “retaining” language is meant to convey the idea that the limited expansion portion must be kept in an expanded condition. Read in context of the specification, this language again is relative, and not absolute. Therefore, the proper construction is that the limited expansion portion must be retained in the expanded condition.

The court finds this limitation to mean “keeping the first portion of the cover in the expanded position and further pushing a second portion of the cover against the portion of the separated tissue that lies over it to further expand only such overlying tissue.”

Claim 24 continues with limitation (e):

*(e) Collapsing and removing the soft tissue expander device from the pocket;*

The parties only disagree as to the construction of “collapsed.” Consistent with the earlier reasoning, the court finds this limitation to mean “collapsing and removing the soft tissue expander device from the pocket,” where “collapsed,” at this time and without the knowledge of the “conventional manner,” means the device is empty of fluid.

Limitation (f) of claim 24 reads:

*(f) Severing edges of the expanded layer from surrounding soft tissue to form a differentially expanded tissue flap; and*

The parties agree that the flap is separated from the surrounding soft tissue during this step. The main dispute is whether this step limits the creation of a flap to one separated at all but one edge. The court disagrees with defendants that this claim requires all but one edge of the flap to be severed, as there is no such limitation in the claim language. Particularly, after considering the principles of claim differentiation, it is notable that claim 25 requires “retaining one edge of the tissue flap connected to surrounding tissue.” In light of this language, to maintain all claims as relevant, it is assumed that claim 24 is broader than claim 25 and can apply to situations where more than one edge remains connected to the surround tissue.

The court finds this limitation to mean “separating dividing lines of the expanded layer from the soft tissue along the outer points of the expanded tissue layer to render it capable of being used to cover an area greater than its original area.”

Finally, claim 24 concludes:

*(g) Flattening and applying the tissue flap to a recipient area larger than the area of the separated layer.*

The parties agree that the tissue is to be applied to a recipient area larger than the original area. Nowhere in the patent does it appear that claim 24 must apply only to planar recipient areas. In the written description, it is noted several times that this method would be appropriate for breast mound reconstruction, a non-planar recipient area. Col. 1, lines 48-50; col. 7, lines 39-

40. Therefore, “flattening” must, by implication, require the tissue to be placed onto the surface of the recipient area and the folds and wrinkles smoothed or flattened out.

Accordingly, the court finds this limitation to mean “smoothing and applying the differentially expanded tissue flap to a recipient area larger than the area of separated tissue.”

**L. Claim 25**

*The method of claim 24 including the steps of retaining one edge of the tissue flap connected to surrounding tissue, moving the flap away from the edge so that it overlies an adjacent recipient area and applying the flap to such area.*

The court finds this limitation to mean “keeping in position one line of intersection between the tissue flap and tissue that extends on all sides of and joins to the tissue flap, moving the flap in a direction other than towards the intact border so that it covers a receiving area near to the differentially expanded tissue flap and applying the flap to such area.”

**IV. CONCLUSION**

The claims in the ‘780 patent which are disputed are construed as set forth above. An Order consistent with this Memorandum Opinion will be entered.

By the court,

---

/s/ Joy Flowers Conti  
Joy Flowers Conti  
United States District Judge

Dated: February 23, 2006  
cc: Attorneys of Record